IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventor	**:**	**Olivier Gerard et al.**
Application No.	**:**	**10/596,434**
Filed	**:**	**June 13, 2006**
For	**:**	**SYSTEM FOR GUIDING A MEDICAL INSTRUMENT IN A PATIENT BODY**

APPEAL BRIEF

On Appeal from Group Art Unit 3768
Examiner Vani Gupta

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I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands by virtue of an assignment recorded June 13, 2006 at reel 017773, frame 0794.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

This application was originally filed with Claims 1-14 which are pending and stand finally rejected by an Office Action mailed December 9, 2009. Claims 1-14 are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendments or other filings were submitted in response to the final rejection mailed December 9, 2009. A notice of appeal was timely filed on February 17, 2010.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The subject of the present invention is a system for image guidance of an invasive medical instrument by the fusion of two dimensional (2D) x-ray images with three dimensional (3D) ultrasound images. Different

types of imaging system technologies are used for medical imaging, such as x-ray, CT, ultrasound, nuclear, and MRI imaging systems. Each of these different technologies is referred to as a different "modality" and each modality provides its own unique imaging attributes. X-ray, for example, does well at imaging bone structure but not at imaging soft tissue. Ultrasound, on the other hand, is well suited for imaging soft tissue but does not image bone. It is desirable in a number of applications such as medical instrument guidance to utilize the advantages of different modalities in one image. For example, the bone structure in the image gives the surgeon anatomical landmarks within the body to guide the navigation while the procedure operates on specific soft tissue structure. The technique of combining images of different modalities into one image is referred to as image fusion or multi-modality imaging. The present technique is a way to provide bi-modality images from x-ray and ultrasound for the guidance of a medical instrument.

The problems inherent in multi-modality image fusion are significant, however, since the image data of the tissue and bone in the images two modalities must be precisely aligned to form a distinct image of the structures in the body. Image distortion and noise in the images make the problem difficult, and the motion of tissues in the body such as the beating of the heart add further complexity. When 3D image datasets

are used, the large volume of data involved can produce a fused image which is less effective than one from a single modality alone. The present inventors have approached this problem by simplifying the image data in several ways. One is to use only 2D x-ray images instead of a 3D x-ray dataset, thus significantly reducing the amount of x-ray image data that needs to be spatially aligned. A second is to reduce the 3D ultrasound image data involved to a selected region of interest around the medical instrument in the body. The combination of these two approaches greatly reduces the complexity, and hence improves the robustness, of the fusion of the two types of image data.

As just mentioned, in order to fuse the image data from two different modalities, it is necessary to achieve spatial alignment of the body structures depicted in the two types of image data. An effective way to provide the locational information needed for spatial alignment is to use a 3D spatial navigation system such as an optical or electromagnetic navigation system. Such spatial navigation systems employ sensors attached to the different components of the systems. The navigation system acquires the spatial coordinates of the sensors in three dimensional space in the coordinate system of the navigation system. For an electromagnetic navigation system the coordinates are coordinates in the electromagnetic field radiated by the navigation system. The

commonly based coordinates of the navigation system are then used to relate the relative positions of the systems, instruments, and patient in the common coordinate geometry. With a relationship of coordinates thus established, the systems can then fuse the image data of the imaging modalities to be commonly spatially aligned. The use of all of these sensors, and the processing of the sensor data, can be quite complex. The present inventors have also simplified localization in their system, as described on page 8 of the specification. In one embodiment only a single active localizer is needed, which is for the ultrasound probe. In the second embodiment no active localizer is needed at all and radio opaque markers are used by image processing. In both embodiments no localizer is needed for the x-ray images, as the coordinate system of the x-ray system is used for spatial localization and not that of a navigation system. Accordingly, a bi-modal image guidance system of the present invention is less complex and more robust than those of the prior art, and is simpler for the surgeon or interventionist to use.

Independent Claims 1 and 14 and dependent Claim 12 are supported by the drawings and specification as seen by reference numerals (#) of the drawings and the specification text (pg., ln) as follows:

1. A medical system comprising:

a medical instrument {#4} to be guided in a patient body {pg. 2, ln 13},

X-Ray acquisition means {#5} for acquiring a two-dimensional X-ray image of said medical instrument {pg. 2, ln 14-15},

ultrasound acquisition means {#9} for acquiring a three-dimensional ultrasound data set of said medical instrument using an ultrasound probe {pg. 3, ln 16-17},

means {#11} for providing a localization of said ultrasound probe within a referential of said X-ray acquisition means {pg. 7, ln 25 to pg. 8, ln 18},

means {#12} for selecting a region of interest around said medical instrument in the three-dimensional ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition means {pg. 9, ln 28 to pg. 10, ln 27},

means {#13} for converting said first localization of said region of interest within said referential of the ultrasound acquisition means into a second localization of said region of interest within said referential of the X-ray acquisition means, using said localization of the ultrasound probe {pg. 9, ln 21-26; pg. 10, ln 28-33},

means {#14} for generating and displaying a bi-modal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization {pg. 10, ln 2 to pg. 12, ln 6}.

14. A method of guiding a medical instrument in a patient body, comprising the steps of:

acquiring a two-dimensional X-ray image of said medical instrument using an X-ray acquisition system {#60; pg. 14, ln 19-20},

acquiring a three-dimensional ultrasound data set of said medical instrument using said ultrasound probe and an ultrasound acquisition system {#61; pg. 14, ln 21-22},

localizing said ultrasound probe in a referential of said X-ray acquisition system {#62; pg. 14, ln 23},

selecting a region of interest of said medical instrument within said 3D ultrasound data set, that define a first localization of said region

of interest within a referential of said ultrasound acquisition system {#63; pg. 14, ln 24-26},

converting said first localization within said referential of said ultrasound acquisition system into a second X-Ray localization within said referential of the X-ray acquisition system {#64; pg. 14, ln 27-28},

generating and displaying a bimodal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization {#65; pg. 14, ln 29-31}.

12. A system as claimed in claim 11, comprising controlling means for periodically triggering the probe localization means {pg. 13, ln 1-14}.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether Claims 1-11, 13 and 14 were correctly rejected under 35 U.S.C. §103(a) as being unpatentable over US pat. pub. no. 2002/0018588 (Kusch) in view of US pat. 6,996,430 (Gilboa et al.)

B. Whether Claim 12 was correctly rejected under 35 U.S.C. §103(a) as being unpatentable over Kusch in view of Gilboa et al. and further in view of US pat. 5,368,032 (Cline et al.)

VII. ARGUMENT

A. Whether Claims 1-11, 13 and 14 were correctly rejected under 35 U.S.C. §103(a) as being unpatentable over US pat. pub. no. 2002/0018588 (Kusch) in view of US pat. 6,996,430 (Gilboa et al.)

The Kusch patent fails to show or suggest the last four elements of Claim 1, the means for providing, the means for selecting, the means for converting, and the means for generating. The Kusch patent fails to show or suggest the last four steps of Claim 14, the localizing, the selecting, the converting, and the generating and displaying.

Kusch is producing a fusion of a 3D x-ray image dataset and a 3D ultrasound image dataset. See the first four lines of paragraph [0027] of Kusch. Kusch provides locational information using an optical navigation system with cameras 4,5 that interpret a reference element 6 attached to the x-ray apparatus 1 and a reference element 7 attached to an ultrasound scanner 24. See the last line of page 2 through the end of paragraph [0027] A navigation computer 9 interprets the camera images and registers reference elements of the two systems to a “reference coordinate system K” of the navigation system. See paragraph [0028]. With the attitudes of the 3D x-ray image dataset and the 3D ultrasound image dataset now identified in the reference coordinate system K, the two 3D image datasets are fused together into one image dataset. See paragraph [0029].

It is seen that Kusch is not fusing a 2D x-ray image with a 3D ultrasound data as called for by Claims 1 and 14. Instead, Kusch is fusing a 3D x-ray dataset with a 3D ultrasound image dataset. Kusch does not

have means for providing a localization of an ultrasound probe within a referential of an x-ray acquisition means. The Examiner contends that this is found in paragraphs [0027]-[0028] of Kusch. However, it is seen that Kusch plainly states in paragraph [0028] that his two 3D image datasets are registered in the "reference coordinate system K" of the navigation system. Likewise, these two paragraphs do not describe localizing an ultrasound probe in a referential of an x-ray acquisition system as called for by Claim 14.

Claim 1 calls for means for selecting a region of interest around a medical instrument within a 3D ultrasound data set. The Examiner contends that this is found in paragraphs [0022]-[0030] of Kusch with specific reference to reference elements 7 and 8. However paragraph [0027] and the drawing figure in Kusch show that reference element 7 is the marker attached to the handle of the ultrasound scanner 24 and reference element 8 the is attached to the body of the patient. These two elements are imaged by cameras 4,5 and used for registering the ultrasound data and the patient in the coordinate system K. There is no region of interest of a medical instrument in Kusch because no medical instrument is imaged by Kusch. Hence there can be no region of interest of a medical instrument within a 3D ultrasound dataset in Kusch because Kusch does not image an instrument. Likewise, there is no selecting a

region of interest of a medical instrument within a 3D ultrasound dataset as called for by Claim 14.

Claim 1 calls for means for converting a first localization of the selected region of interest in the referential of the ultrasound acquisition means into a second localization of the region of interest within the referential of an x-ray acquisition means. The Examiner contends that this is found in paragraphs [0027]-[0030] of Kusch. But as just seen above, there is no selected region of interest around a medical instrument in Kusch, nor is there conversion to the referential of an x-ray acquisition means because Kusch uses the coordinates of reference coordinate system K of his navigation system. Likewise, Kusch does not show converting a first localization within the referential of an ultrasound acquisition system into a second x-ray localization within a referential of an x-ray acquisition system.

Lastly, Claim 1 calls for means for generating and displaying a bi-modal representation of a medical instrument in which a 2D X-ray image and 3D ultrasound data included in a region of interest are combined using a second x-ray localization. As mentioned above, Kusch is combining two 3D datasets. There is no selection of a region of interest of a medical instrument in a 3D ultrasound image. There is no use of a second x-ray localization because the image fusion is done in the

reference coordinate system K of the Kusch navigation system. Likewise there is no generating and displaying a bi-modal representation of a medical instrument in which a 2D X-ray image and 3D ultrasound data included in a region of interest are combined using a second x-ray localization as called for by Claim 14.

Gilboa et al. does not show or suggest these four elements of Claim 1 and four steps of Claim 14 either. Gilboa et al. also use a navigation system 130 with sensors 132-138 attached to a fluoroscope 110, an ultrasound transducer 120, a treatment-applying probe 170, and the patient. See col. 8, lines 56-61. The location signals from the navigation system are fed to a computer 140. The coordinate data allows the fluoroscopic image to be displayed on a fluoro monitor 192 in a defined "preferred line of sight" (PLOS). The ultrasound image is displayed as a projection image in a known relationship to the PLOS on an ultrasound display 160. The theory is that a clinician can look at the fluoroscopic image on monitor 192 with the defined PLOS and then, when looking at the ultrasound image on display 160, the clinician will have a sense of the orientation of the ultrasound image in relation to that of the fluoroscopic image.

The fluoroscopic and ultrasound images in Gilboa et al. are not fused, but shown separately on separate monitors. Thus, the means for

generating and displaying a bi-modal image of Claim 1 and the generating and displaying step of Claim 14 are both absent from Gilboa et al. There is no localizing or means for localizing an ultrasound probe in a referential of an x-ray acquisition system since Gilboa et al., like Kusch, use a navigation system to establish the spatial coordinates of all of their devices. There is no means for selecting a region of interest of a medical instrument or selecting step in Gilboa et al. Gilboa et al. use a “treatment-applying probe 170” which is mentioned in col. 8, lines 59-60. But Gilboa et al. apparently cannot image this probe. Instead, they acquire the position of the probe 170 from its sensor 138 and use this position information to project a graphic symbol representing the probe onto the ultrasound display 160. See col. 10, lines 14-17. There is clearly no selection of a region of interest of the probe 170 in a 3D ultrasound image in Gilboa et al. Lastly there is no converting of a localization within the referential of an ultrasound acquisition system into a second x-ray localization within the referential of an x-ray acquisition system. As previously mentioned, Gilboa et al. use the common coordinate system of their locating system 130. It is thus seen that Gilboa et al., like Kusch, does not show or suggest the last four elements and steps of Claims 1 and 14. For these reasons it is respectfully submitted

that Claims 1 and 14, and their dependent Claims 2-13, are patentable over Kusch and Gilboa et al.

B. Whether Claim 12 was correctly rejected under 35 U.S.C. §103(a) as being unpatentable over Kusch in view of Gilboa et al. and further in view of US pat. 5,368,032 (Cline et al.)

Claim 12 recites the use of controlling means for periodically triggering probe localization means. Cline et al. was cited to show this, with reference to the footswitch 79 in Fig. 1. However the text of Cline et al. says in col. 3, lines 49-51 that the footswitch is used to trigger acquisition of an image by an MRI system. The footswitch has nothing to do with probe localization. The ultrasound transducer 73 used in Cline et al. does not perform imaging. It is a therapy probe which heats tissue in the body by concentrating ultrasound energy at its focal point. Thus, it is respectfully submitted that Claim 12 is patentable over the three cited references because Cline et al. fails to show the element for which it was cited.

Cline et al. fails to show the four elements of Claims 1 and 14 which are absent from Kusch and Gilboa et al. There is no image fusion in Cline et al., no x-ray system, no ultrasound image, no selecting a region of interest of a medical instrument, no coordinate conversion, and no bi-modal imaging. For all of these reasons it is respectfully submitted that Claims 1-14 are patentable over Kusch, Gilboa et al., and Cline et al.

VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 1-14 are patentable over any combination of Kusch, Gilboa et al., and Cline et al. The last four elements of the independent Claims 1 and 14 are absent from all three references. Accordingly, it is respectfully requested that this Honorable Board reverse the grounds of rejection of Claims 1-14 of this application which were stated in the December 9, 2009 Office action being appealed.

Respectfully submitted,

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April 15, 2010

APPENDIX A: CLAIMS APPENDIX

The following Claims 1-14 are the claims involved in this appeal.

1. (original) A medical system comprising:

a medical instrument to be guided in a patient body,

X-Ray acquisition means for acquiring a two-dimensional X-ray image of said medical instrument,

ultrasound acquisition means for acquiring a three-dimensional ultrasound data set of said medical instrument using an ultrasound probe,

means for providing a localization of said ultrasound probe within a referential of said X-ray acquisition means,

means for selecting a region of interest around said medical instrument in the three-dimensional ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition means,

means for converting said first localization of said region of interest within said referential of the ultrasound acquisition means into a second localization of said region of interest within said referential of the X-ray acquisition means, using said localization of the ultrasound probe,

means for generating and displaying a bi-modal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization.

2. (original) A system as claimed in claim 1, wherein said means for selecting a region of interest are intended to define a reference plane in which a part of said medical instrument is included.

3. (original) A system as claimed in claim 2, wherein said region of interest is a 2D ultrasound image obtained by sampling said 3D ultrasound data set over said reference plane.

4. (original) A system as claimed in claim 2, wherein said region of interest is obtained by cropping a 3D ultrasound data subset, which lies

behind said reference plane or by cropping a slab which is formed around said reference plane.

5. (original) A system as claimed in claim 4, wherein said generating means are intended to generate a volume rendered view of said region of interest within said 3D ultrasound data set.

6. (original) A system as claimed in claim 1, wherein said probe localization means are intended to localize an active localizer, which has been arranged on said ultrasound probe.

7. (original) A system as claimed in claim 1, wherein said ultrasound probe is equipped with at least three non aligned and interdependent radio-opaque markers and

said localization means are intended to localize said markers in at least a first 2D X-ray image having a first orientation angle in said referential.

8. (original) A system as claimed in claim 7, wherein said localization means are intended to further localize said markers in a second 2D X-ray image having a second orientation angle in said referential.

9. (original) A system as claimed in claim 1, wherein said selection means comprise means for detecting said medical instrument within said region of interest of the 3D ultrasound data set and

said generating means are intended to give to the points of the detected medical instrument in said bimodal representation the X-ray intensity values of the corresponding points in the 2D X-Ray image.

10. (original) A system as claimed in claim 1, comprising

means for segmenting a wall tissue region in the 3D ultrasound data set and

said generating means are intended to give to the points belonging to said wall tissue region the ultrasound intensity values of the corresponding points of said region of interest.

11. (original) A system as claimed in claim 1, wherein the X-Ray acquisition means are intended to provide live two-dimensional X-Ray images and the ultrasound acquisition means live three-dimensional ultrasound data sets.

12. (original) A system as claimed in claim 11, comprising controlling means for periodically triggering the probe localization means.

13. (original) A system as claimed in claim 11, comprising
means for compensating a motion between a current three-dimensional ultrasound data set acquired at a current time and a previous three-dimensional ultrasound data set acquired at a previous time.

14. (original) A method of guiding a medical instrument in a patient body, comprising the steps of:
acquiring a two-dimensional X-ray image of said medical instrument using an X-ray acquisition system,
acquiring a three-dimensional ultrasound data set of said medical instrument using said ultrasound probe and an ultrasound acquisition system,
localizing said ultrasound probe in a referential of said X-ray acquisition system,
selecting a region of interest of said medical instrument within said 3D ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition system,
converting said first localization within said referential of said ultrasound acquisition system into a second X-Ray localization within said referential of the X-ray acquisition system,
generating and displaying a bimodal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization.

APPENDIX B: EVIDENCE APPENDIX

None. No extrinsic evidence has been submitted in this case.

APPENDIX C: RELATED PROCEEDINGS APPENDIX

None. There are no related proceedings.